**Suspected Multiple Sclerosis relapse following administration of COVID-19 vaccine\***

Local Identification Number: Adverse Event Reference Number:

Patient Initials: Patient Age: Patient Sex:

Ethnicity:

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| **Source of information** | | | |
| Name of the person reporting |  | Position (e.g. specialty and grade) |  |
| Hospital / Practice |  | Email address |  |

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| **Patient Background** | |
| Past Medical History: | |
| Regular and recent medications: | |
| Infectious illness in the last six weeks: | Yes/ No/ Unsure |
| Other vaccination received in the last six weeks: | Yes/ No/ Unsure |
| Previous adverse neurological reaction to a vaccine: | Yes/ No/ Unsure |
| History of neurological disease (excluding MS): | Yes/ No/ Unsure |
| Immunosupression at the time of vaccination: | Yes/ No/ Unsure |
| If Yes to any above, please provide details: | |

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| **Covid-19 Status** | |
| Previous diagnosis of Covid-19: | Yes, once/  Yes, more than once/ No/ Unsure |
| If Yes, date of onset: | Date: |
| If Yes, means of diagnosis: | PCR/ Antibody/ Clinical/ Other |

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| **Vaccination Details** | |
| 1st vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| 1st vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| Date of neurological symptoms onset | Date: |

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| **Case Definition** | |
| New signs and/or symptoms of acute inflammatory demyelinating event in the central nervous system of minimum 24-hour duration | Yes/No/ Unsure |
| PLUS Diagnosis of MS or Clinically Isolated Syndrome (CIS) | Yes/No/ Unsure |
| PLUS Unknown Aetiology | Yes/No/ Unsure |

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| **Multiple Sclerosis Background** | |
| Type of MS: CIS/ RRMS/ SPMS/ PPMS | Year of diagnosis: |
| Number of relapses in the last two years (or since the diagnosis, if more recent): | |
| Date and anatomical location of the most recent relapse: | |
| Current medications: | |
| Change to the regular medications in the last year: Yes/ No/ Unsure  If Yes, please provide reasons: | |
| Most recent MRI brain:  Date: | |
| Most recent MRI spine:  Date: | |
| **This relapse:** | |
| Are the reported symptoms and signs NEW to the patient (i.e. not an exacerbation of chronic symptoms or a recurrence of previously experienced symptoms? | Yes/ No/ Unsure |
| Are there new demyelinating changes on the imaging? | Yes/ No/ Unsure |
| If Yes, do these changes correspond to the new symptoms and/or signs? | Yes/ No/ Unsure |
| Further details: | |

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| **Symptoms and Signs** |
| Time from onset to peak symptoms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Suspected CNS location: optic nerve/ other cranial nerves/cerebral hemisphere/ cerebellum/ brainstem/spinal cord/ multifocal/ other- specify: |
| Limb weakness with upper motor neuron signs: Yes/ No/ Unsure  Affected limbs (select): RUL/ LUL/ RLL/ LLL |
| Hyperreflexia: Yes/No/Unsure  Affected reflexes (indicate R/L): |
| Sensory disturbance: Paraesthesia/Hypoesthesia/ No/ Unsure  Modality affected: Light touch/ vibration/ proprioception/ pinprick/ temperature  Sensory level: Yes- specify level: \_\_\_\_\_\_\_\_\_\_\_/ No/ Unsure  Please describe distribution: |
| Autonomic dysfunction: Yes (select below)/ No/ Unsure  Bladder dysfunction/ Bowel dysfunction/ Erectile dysfunction/ Other- describe |
| Visual disturbance\*: Yes (select below)/ No/ Unsure  Reduced visual acuity/ RAPD/ eye pain/ loss of colour vision/ photophsia/ Visual field defect |
| Diplopia: Yes/ No/Unsure |
| Cerebellar signs: Yes/ No/ Unsure  Nystagmus/ Ataxia/ Intention tremor/ Dysarthria/ Other- describe |
| Other relevant symptoms and signs, including systemic features: |
| \*If reporting optic neuritis, please provide details of opthalmological assessment, including slit lamp/ fundoscopy: |

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| **Assessment and investigations to exclude other causes** (please indicate which of the following have been considered, and give details at the bottom) | |
| **Clinical assessment** (if abnormal give details at the bottom) | |
| Symptoms and/or signs of preceeding infection (including, but not limited to: fever, riggors, myalgia, arthralgia, nasal congestion, sore throat, cough, SOB, abdominal pain, N&V, diarrhoea, dysuria, urinary frequency, urinary odour, unusual vaginal discharge, skin redness, soreness or swelling) or physiological stress  Previous episode of MS relapse in the same CNS location  MS relapse in <30 days preceeding this event  Poor compliance with medications  Systemic symptoms in response to the Covid-19 vaccine (including, but not limited to: fever, myalgia, arthralgia, malaise, fatigue) | Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure |
| **Laboratory investigations** (if abnormal give details at the bottom) | |
| CRP  Urea and Electrolytes  White cell count  Urine Culture and Microscopy  Respiratory Viral Screen  Covid-19 Serology/PCR  Where relevant:  Blood culture  Stool culture  CSF Biochemistry, Bacteriology, Virology\* incl. JCV | Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal |
| CSF Biochemistry**:** CSF Protein: \_\_\_\_\_\_\_ Serum:CSF Glucose Ratio: \_\_\_\_\_\_\_\_\_  CSF RCC: \_\_\_\_\_\_\_\_\_ CSF WCC: \_\_\_\_\_\_\_\_ CSF differential: \_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_ | |
| \*Please list the pathogens tested within the panels: | |
| Any other relevant laboratory results: | |
| **Radiological studies** (if abnormal give details at the bottom) | |
| MRI spine with GAD  MRI brain with GAD  Optical Coherence Tomography  CXR/ CT Chest | Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal |
| **Visual Evoked Potentials** | Normal/ Unknown/ Not Done/ Abnormal |
| **Details of any abnormal findings:** | |
| **Please describe if there are any recognised triggers for this relapse:** | |

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| **Treatment** (including dose and duration) |
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| **Patient Outcome** |
| Date of last follow-up (if none, write none): |
| Maximum level of care required:  Outpatient/ Medical Inpatient/ High Dependency Unit/ Intensive Care Unit |
| Patient alive at last follow-up: Yes/ No  If No, was the neurological adverse event included on the death certificate: Yes/ No/ Unknown  If relevant, date of death: |
| Outcome at the last follow up (circle):  Complete resolution / Incomplete resolution / No improvement / Re-occurrence / Other sequalae  If symptoms resolved, time from the onset to the resolution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Modified Ranking Scale: Before adverse event:\_\_\_\_\_\_\_ At the last follow-up: \_\_\_\_\_\_ |
| Expanded Disability Status Scale (or an alternative- please specify):  Before adverse event:\_\_\_\_\_\_\_ At the last follow-up: \_\_\_\_\_\_ |
| Details: |

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| **Subsequent COVID-19 Vaccinations** | |
| Has this patient received any further COVID-19 vaccines after the development of the neurological adverse event? | Yes/ No/ Unsure |
| If Yes: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| If Yes, Outcome: No adverse event/ Re-occurrence of the same adverse event/ Development of another neurological adverse event/ Worsening of previously unresolved neurological adverse event/ Other sequelae  Date the outcome was last known: | |
| Other details: | |

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| **Proposed Case Classification for Multiple Sclerosis Relapse (Level of Certainty)** | | | | |
| *This will be completed by the assessors based on the information provided.* | | | | |
| **Level 1** | **Level 2** | **Level 3** | **Level 4** | **Not a case** |
| Meets Case Definition AND | | | Reported case with insufficient information to meet level 3 criteria | Does not meet level 3 criteria with sufficient information reported |
| Objective clinical and radiological evidence of new CNS demyelination  AND  Alternative causes excluded by means of clinical and laboratory assessment | Objective clinical and radiological evidence of new CNS demyelination  AND  Alternative causes excluded by means of clinical assessment | Objective clinical evidence of new CNS demyelination in the absence of imaging  AND  Alternative causes excluded by means of clinical and/or laboratory assessment |

\* This reporting form is based on the The Brighton Collaboration Transverse Myelitis Case Definition Companion Guide (Law; 2020) and Transverse Myelitis Consortium Working Group (*Neurology* 2002*;* 59.4: 499-505) as well as Polman, Chris H., et al. "Diagnostic criteria for multiple sclerosis: 2010 revisions to the McDonald criteria." *Annals of neurology* 69.2 (2011): 292-302.